

REMARKS

Claim 1 is the only pending claim.

Reconsideration of the above-captioned application in light of the following remarks is respectfully requested.

Claim 1 stands rejected under 35 U.S.C. §101 as the claimed invention is allegedly not supported by either a specific asserted utility or a well established utility and further that the claimed method allegedly would be "...impossible to carry out with compounds embraced by the claim but not described at all in the disclosure. What are the starting materials and reaction conditions to prepared [sic] the same?"

Applicants respectfully submit that Claim 1 is supported by a specific asserted utility, that utility being the prevention and treatment of inflammatory diseases. This utility is specifically set forth in the claim and supported by the specification. The specification provides support for the use of two structurally different GABA analogs used for the prevention and treatment of inflammatory diseases. Further, the specification provides reference to United States Patent Numbers 4,024,175 and 5,563,175, which teach the preparation of numerous GABA analogs including gabapentin and pregabalin, respectively.

Claim 1 also stands rejected under 35 U.S.C. §112, first paragraph, as it is alleged that since the claimed invention is not supported by either a specific asserted utility or a well established utility, that one skilled in the art clearly would not know how to use the claimed invention. Applicants respectfully submit that the claimed invention is supported by a specific asserted utility as set forth above in response to the rejection under 35 U.S.C. § 101.

Furthermore, Applicants respectfully submit that the specification provides adequate description regarding the range of effective amounts of the GABA analogs, which could be given to a subject in order to prevent and treat inflammatory diseases. Specifically, Applicants respectfully directs the Examiner's attention to page 4, lines 2-16 of the specification, wherein general support is provided for dosing of a subject with a GABA analog. Further, referring to page 5, lines 12-16, support for both routes of administration of the GABA analog and dosing support is provided. Furthermore, Applicants respectfully submit that one of ordinary skill in

the art, such as a medical practitioner, would easily be able to identify and administer an amount of a GABA analog effective to prevent or treat an inflammatory condition.

Accordingly, Applicants respectfully submit that the rejections of Claim 1 under 35 U.S.C. § 101, and 35 U.S.C. § 112, first paragraph, have been overcome and respectfully request reconsideration of these rejections.

Claim 1 stands rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Specifically, the phrase "preventing and treating inflammatory diseases" was held to be indefinite for not being clear which specific inflammatory diseases are prevented and treated by the claimed method. Applicants respectfully submit that inflammatory diseases are defined in the specification on page 1, lines 9-22. Applicants respectfully submit that the definition of "inflammatory diseases" set forth therein sufficiently defines "inflammatory diseases" for the purposes of rendering Claim 1 definite.

Further, the phrase "to a subject in need" was also held to be indefinite as to the definition of the word "subject" to be treated. Applicants respectfully submit that the phrase "to a subject in need" is definite in light of the language set forth on page 5, line 24 of the specification, wherein subjects are defined as mammals, including humans.

The phrase "anti-inflammatory amount" was also held to be unclear. Applicant has amended Claim 1 to clarify that "an effective anti-inflammatory amount of a GABA" is administered.

The phrase "GABA analog" was also held to be indefinite. Applicant's respectfully submit that the term "GABA-analog" is clearly defined within the specification as set forth on page 4, lines 1-4. Furthermore, United States Patent Numbers 4,024,175 and 5,563,175, both of which are incorporated by reference in the application, teach numerous other GABA-analogs. Therefore, Applicants respectfully submit that the phrase "GABA-analog" is definite.

Claim 1 also stands rejected under U.S.C. § 112, first paragraph, as it is alleged that the specification, "while being enabling for a method of treating the particular inflammation by using the particular GABA analogs as indicated in the Examples given by the disclosure, does not reasonably provide enablement for:

- Treating other inflammatory diseases

- In any possible subject
- By using all possible GABA analog or
- Preventing any inflammatory disease in any subject by using any GABA analog".

Applicants respectfully submit that Claim 1 is fully enabled, as written, without limitation to the particular analogs set forth in the Examples. 35 U.S.C. § 112, first paragraph, states "[t]he specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention."

Applicants respectfully submit that presently pending Claim 1 meets all of the requirements set forth in 35 U.S. C. §112, first paragraph. Specifically, 35 U.S.C. §112, first paragraph, requires that "[t]he specification shall contain a written description of the invention,...". In the present application, Claim 1 defines a method for preventing and treating inflammatory diseases comprising administering to a subject in need of treatment and effective anti-inflammatory amount of a GABA analog. As stated above, the specification provides sufficient enablement for each aspect of the claimed invention. Specifically, the specification provides enablement for preventing and treating inflammatory diseases (as stated in the specification on page 1, lines 9-22) comprising administering to a subject in need of treatment (as set forth in the specification on page 5, line 24) and effective anti-inflammatory amount (as set forth in the specification on page 4, lines 12-16) of a GABA analog (as described in the specification on page 2, line 10- page 3, line 23 and in United States Patent Number 4,024,175 and 5,563,175, both of which were incorporated by reference).

35 U.S.C. §112, first paragraph, also requires that the specification shall contain a written description of the invention, "and the manner in process of making and using it, in such full, clear, concise, and exact terms as to enable to any person skilled in the art to which it pertains, or with which it is most nearly connected to make and use the same,...". Applicants respectfully submit that the specification of the present application does provide a full written description of the manner and process of making and using the claimed invention. As is previously stated above, Applicants submit that one of ordinary skill in the art using the present

specification would readily identify those inflammatory diseases which could be treated according to the present invention in a suitable subject, such as a human, by administering a GABA analog in accordance with the compound set forth in the specification and in the patents incorporated therein by reference. Further, as stated above, the specification provides full, clear, concise, and exact terms which would enable any person skilled in the art to identify a subject in need of prevention and treatment of an inflammatory condition by administering to that subject an effective anti-inflammatory amount of a GABA analog as set forth in the specification.

Accordingly, Applicants respectfully submit that the rejection of Claim 1 under 35 U.S.C. §112, first paragraph has been overcome.

Claim 1 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Nagai. Applicants respectfully request reconsideration of this rejection.

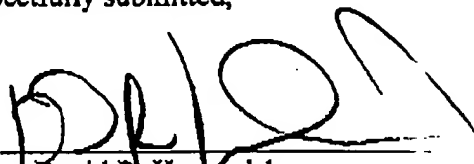
It is stated in the Office Action that Nagai teaches gamma amino butyric acid and its salts and the use thereof as an anti-inflammatory accelerating agent. It is further stated in the Office Action that it would be obvious to consider that GABA analogs are useful in the treatment of inflammation given the close structural relationship between GABA and its analogs. Applicants respectfully submit that the Nagai reference provides neither any teaching nor suggestion for utilizing GABA analogs for the treatment and prevention of inflammatory diseases as set forth in Claim 1. The fact that one of ordinary skill in the art has the capabilities to arrive at the claimed invention is not the proper test for whether one of ordinary skill in the art would have arrived at the claimed invention based on the teachings of the prior art. An obviousness rejection cannot be predicated on the fact that one of ordinary skill in the art would have the capabilities to arrive at the invention. In the present case, since there is neither teaching nor suggestion in the Nagai reference to utilize GABA analogs for the treatment of inflammation, the only teaching or suggestion for utilizing the GABA analogs thus comes from utilizing Applicants' claimed invention to make the leap from using only GABA and its salts as an accelerating agent for the treatment of inflammation to the use of GABA analogs for the treatment of inflammation. This hindsight use of Applicants' claims is improper as a matter of law. Accordingly, Applicants respectfully submit that the rejection of Claim 1 under 35 U.S.C. §103(a) has been overcome. Applicants respectfully request reconsideration and withdrawal of the rejection.

In view of the foregoing remarks, reconsideration of the rejection and advancement of the case to issue are respectfully requested.

The Commissioner is authorized to charge any fee or credit any over payment in connection with this communication to our Deposit Account No. 23-0455.

Respectfully submitted,

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